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# Evaluating the Bioavailability of Carbamazepine Using a Novel SNEDDS Formulation

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# Evaluating the Bioavailability of Carbamazepine Using a Novel SNEDDS Formulation

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## Background of the Problem

Carbamazepine (CBZ) is an anticonvulsant primarily used to treat seizures, glossopharyngeal neuralgia, trigeminal neuralgia, and acute or mixed episodes of manic depression. Adverse effects of its use include dizziness, drowsiness, nausea, headache, vomiting, and ataxia. CBZ is lipophilic with overall poor solubility and resultant bioavailability.

Four classes of solubility exist:

- Class I: high permeability; high solubility
- Class II: high permeability; low solubility
- Class III: low permeability; high solubility
- Class IV: low permeability; low solubility

Carbamazepine is a Class II drug. To fix this problem, researchers have been studying the use of self nano-emulsifying drug delivery systems (SNEDDS). Using a SNEDDS formulation decreases particle size to increase bioavailability.<sup>1</sup> Additionally, a SNEDDS formulation uses oil emulsification to deliver these very small particles to the bloodstream more efficiently by increasing drug dissolution rate.<sup>2</sup>

## Objective

The objective of this study is to compare the bioavailability of a novel carbamazepine SNEDDS formulation to that of an existing FDA approved CBZ suspension.

## Alternative Hypothesis

The novel SNEDDS formulation will have a statistically significant increase in bioavailability when compared to the existing suspension.



## Project Timeline

- **Fall 2013-** Submission of Research Proposal
- **Spring 2014-** IACUC Approval, Order Animals (~16)
- **Fall 2014-** Complete Experimental Methods, Collect Samples and Analyze Data
- **Spring 2015-** Data Interpretation, Repeat Experiments if Necessary
- **Fall 2015-** Submit Final Research Documentation and Prepare Presentation
- **Spring 2016-** Present in Professional Venue and for Research Seminar (CU)

## Future Direction

Pending time and resources, research can extend beyond analysis of blood plasma concentrations of carbamazepine. Passing through the blood brain barrier is another obstacle present to carbamazepine. If we could also analyze the difference in tissue drug concentration from crossing this barrier, further support for use of the SNEDDS formulation would be uncovered.

## Proposed Methods and Analysis

**Study Design:** Our study design is a randomized controlled crossover experiment in a rat model.

**Sample:** Our sample will be comprised of 10-12 Sprague-Dawley rats divided equally into two groups.

### Measurement & Data Collection:

For the study, a tail vein method will be used to collect sample. The blood sample can be taken by a small incision on a rat's tail. After administration, blood samples are collected into heparinized centrifuge tubes at 5, 10, 15, 20, 30, 45, 60, 90, and 120 minutes and stored at -20°C until ready for analysis.<sup>3</sup> Once samples have been collected, our study will utilize a CEDIA kit to analyze blood serum carbamazepine levels.<sup>4</sup> This method involves Enzyme-Linked Immunosorbent Assay (ELISA) analysis.

**Statistical Analysis:** The data we will be collecting is continuous data. It is being collected from two independent samples. Thus, an unpaired t-test will be used to compare the significance between the two sets of data.

## Limitations

- Using a small sample size will lower statistical power of the results
- A rat model may not be generalizable to humans (can only make inferences)

## References

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